

## REMARKS

The pending Office Action addresses and rejects claims 1-8, 10-14, 16-21, 23-27, and 29-33. Claims 29-31 were previously withdrawn from consideration. Reconsideration is respectfully requested in view of the following remarks.

### *I. Summary of the Claimed Subject Matter*

Claim 1 recites a biocompatible meniscal repair device. The device includes a biocompatible tissue repair scaffold adapted to be placed in contact with a defect in a meniscus. The tissue repair scaffold comprises a dry laid nonwoven polymeric material, the dry laid nonwoven polymeric material having a density in the range of about 120 mg/cc to 360 mg/cc. The tissue repair scaffold has an initial modulus of elasticity greater than about 1.5 MPa and an initial suture pull-out strength greater than about 6 N. Viable tissue, which has viable cells capable of integrating with native tissue adjacent to the tissue repair scaffold, is disposed on the tissue repair scaffold.

Claim 19 also recites a biocompatible meniscal repair device. The device includes a biocompatible tissue repair scaffold adapted to be placed in contact with a defect in a meniscus. The scaffold includes a dry laid nonwoven polymeric material having a density in the range of about 120 mg/cc to 360 mg/cc, a biocompatible foam, and viable tissue disposed on the tissue repair scaffold. The viable tissue contains viable cells capable of integrating with native tissue adjacent to the tissue repair scaffold and the scaffold provides increased suture pull-out strength and has an initial modulus of elasticity in the range of about 1.5 MPa to 40 MPa.

### *II. The Examiner's Rejection*

Claims 1-8, 10-14, 16-21, 23-27, and 32-33 remain rejected pursuant to 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Publication No. 2002/0127265 of Bowman et al. ("Bowman") and International Patent Publication No. WO 01/85226 of Huckle et al. ("Huckle") as exemplified by Boland et. al. (*J. Macromol. Sci.-Pure Appl. Chem.*, 2001, A38(12), p 1231-1243) ("Boland"). Applicants respectfully disagree with the Examiner's rejection.

The Examiner also continues to assert that Huckle "teaches scaffolds having a density of 120 mg/cm<sup>3</sup>." In particular, the Examiner alleges that:

Page 21 of [Huckle] describes the process of making the nonwoven scaffold. The process begins with a nonwoven felt that has a density of 60 mg/cm, which is plate pressed at high heat with spaces to produce a particular thickness and a density of 93 mg/cm<sup>3</sup>. The felt is further processed by soaking it in polycaprolactone ("PCL"), a well-known polymer. The entire process of making the scaffold results in a final product with a density of 120 mg/cm<sup>3</sup>.

The Examiner acknowledges that:

The instant claims specifically recite that the scaffold comprises a nonwoven polymeric material with a density in the recited range.

However, the Examiner also asserts that:

Independent claims 1 and 19, which recite that the claimed device "comprises" (i.e., open language) the generic dry laid nonwoven polymeric material, do not prohibit the dry laid polymeric material from comprising a coating in order to achieve the recited density. [...]

There is no limitation in the claims as to the form of the nonwoven polymeric material and the specification discloses a number of various forms, including hybrid forms for the material of interest. Further there is no limitation in the specification or the claims prohibiting a PCL coating on the nonwoven polymeric material.

The Examiner alleges that:

Applicant's own specification teaches hybrid nonwoven polymeric materials and the incorporation of polycaprolactone (PCL) into these hybrids.

In this regard, the Examiner attempts to rely on Applicants' disclosure regarding wet laid nonwovens "as permitting a PCL slurry deposition or 'coating' on another type of nonwoven, such as the felt taught by [Huckle], in the same manner as that taught in [Huckle]."

The Examiner then argues that:

Because Applicant's own specification recites embodiments of the claimed invention that encompasses hybrid nonwoven polymeric material, including hybrid nonwoven polymeric material that meets the limitation of that taught by the

prior art with the required density, Applicant's arguments are not persuasive and the rejection is maintained.

Applicants respectfully disagree with the Examiner's arguments.

***III. The Combination of Bowman and Huckle Fails To Teach or Suggest the Claimed Invention***

The cited references, whether taken alone or in combination, fail teach or suggest a nonwoven polymeric material having a density in the claimed range.

**A. Bowman fails to teach or suggest a nonwoven polymeric material having a density in the claimed range.**

Bowman fails to teach or suggest a nonwoven material having a density in the claimed range. In fact, Bowman fails to provide any teaching or suggestion regarding the density of a nonwoven material except for a "mesh material" that is disclosed as being a "low density, or open knitted mesh material." Bowman at paragraph 0066. Moreover, Bowman is directed to scaffold including foam reinforced with a mesh material that has an open structure so that the foam can penetrate the mesh. See Bowman at paragraph 10, FIG. 6. Thus, Bowman fails to teach or suggest a nonwoven material having the claimed density range.

**B. Huckle fails to teach or suggest a nonwoven polymeric material having a density in the claimed range.**

Huckle discloses a "needled felt" with "a density of 93 mg/cm<sup>3</sup>." Huckle at page 21, lines 14-15. Thus, the nonwoven material disclosed by Huckle has a density at least 30% lower than the claimed density range. Huckle therefore fails to teach or suggest a nonwoven material having a density in the claimed range.

Huckle discloses that the felt can be immersed in a PCL solution and then dried. See Huckle at page 21, lines 20-32. According to Huckle, the PCL coating increases the density of the resulting scaffold. This is inapplicable to Applicants' claims. Applicants do not claim a density range of a scaffold, but a particular material used in the preparation of the scaffold (i.e., a nonwoven polymeric material). The resulting scaffold is no longer just a non-woven material. Instead, it is a composite consisting of the original felt material and a coating of dried PCL. In the absence of the PCL coating, the non-woven felt within the composite scaffold would still have its original density of 93 mg/cm<sup>3</sup>. Thus, at best, Huckle discloses a scaffold that includes a

needed felt with a density of 93 mg/cm<sup>3</sup> and a PCL coating. Although the PCL coating allegedly increases the density of the composite scaffold, it does not change the density of the original non-woven material. In contrast, claim 33 requires that the nonwoven polymeric material, itself, has a density in the range of about 120 mg/cc to 360 mg/cc. This density is between 30% and 400% higher than the density of the needed felt disclosed by Huckle. Huckle therefore fails to teach or suggest a nonwoven polymeric material having a density in the range of about 120 mg/cc to 360 mg/cc.

The Examiner argues that claims “do not prohibit the dry laid polymeric material from comprising a coating in order to achieve the recited density.” This is incorrect. While Applicants agree that the claims do not prohibit a coating on the dry laid nonwoven polymeric material, Applicants disagree that a coating can be applied to the nonwoven material “in order to achieve the claimed density,” as argued by the Examiner. The claims specifically require that the dry laid nonwoven polymeric material, itself, has the claimed density. In contrast, Huckle specifically discloses a needed felt that has a much lower density. The mere fact that Huckle also discloses the addition of a PCL coating on the felt does not change the fact that the felt, itself, does not have the claimed density.

As noted above, the Examiner attempts to remedy the deficiencies of Huckle by referring to the various non-woven polymeric materials disclosed in Applicants’ specification. Applicants disclosure of dry laid and wet laid nonwovens, as well as hybrids thereof, does not change the requirements of claim 33. No matter how the nonwoven material might be produced, claim 33 still requires that the nonwoven has a density within a specific range. For example, the disclosure by Applicants of “hybrids” that “can be formed by combining one or more layers of different types of nonwovens by a variety of lamination techniques” in no way changes the requirements of claim 33 regarding the density of the nonwoven polymeric materials themselves. In particular, the claimed method must include a biocompatible tissue repair scaffold including a dry laid nonwoven polymeric material, the dry laid nonwoven polymeric material having a density in the range of about 120 mg/cc to 360 mg/cc. The fact remains that Huckle’s nonwoven material, i.e., the needed felt, simply does not have a density in the claimed range. Huckle therefore fails to teach or suggest a nonwoven polymeric material having a density in the range of about 120 mg/cc to 360 mg/cc.

**C. The combination of Bowman and Huckle fails to teach or suggest a nonwoven polymeric material having a density in the claimed range.**

As discussed above, Bowman and Huckle each fail to teach or suggest a nonwoven polymeric material in the claimed density range. Thus, even if the references were combined, the combination would also fail to teach or suggest Applicants' claimed invention. In particular, the combination of Bowman, which lacks any teaching of a density range, with Huckle, which discloses a nonwoven with a density lower than the claimed range, fails to teach or suggest a scaffold including a nonwoven polymeric material having a density in the range of about 120 mg/cc to 360 mg/cc, as required by claims 1 and 19.

Accordingly, claims 1 and 19 distinguish over the combination of Bowman and Huckle and represent allowable subject matter. Claims 2-8, 10-14, 16-18, 20, 21, 23-27, and 32-33, which depend from either claim 1 or 19, distinguish over the cited art at least because they depend from an allowable base claim.

***IV. Obviousness-Type Double Patenting Rejections Obviousness-Type Double Patenting Rejections***

The Examiner provisionally rejects claims 1-8, 10-14, 16-27, and 32-33 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-14, 17-29, and 32 of co-pending Application No. 11/427,477. The Examiner also provisionally rejects claims 1, 7, 10-14, 19, and 34-27 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1 and 8-11 of co-pending Application No. 11/856,743. The Examiner also provisionally rejects claims 1, 7, 8, 19, 24-27, 32, and 33 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1, 5, 7-9, 12, and 13 of co-pending Application No. 11/856,741.

Applicants believe that all pending claims are allowable. Applicants will file appropriate terminal disclaimers if so warranted. The instant application, however, was filed earlier than the applications that form the basis of the non-statutory double patenting rejections, and thus the Examiner should withdraw the provisional rejections and permit this application to issue as a patent without a terminal disclaimer (MPEP §804).

*V. Conclusion*

Applicants submit that all pending claims are allowable, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicants if such communication is deemed necessary to expedite prosecution of this application.

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Respectfully submitted,

By           /George A. Xixis/            
George A. Xixis  
Registration No.: 38,664  
NUTTER MCCLENNEN & FISH LLP  
World Trade Center West  
155 Seaport Boulevard  
Boston, Massachusetts 02210-2604  
(617)439-3746  
(617) 310-9746 (FAX)  
Attorney for Applicants

1885478.1